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EXAMINER	
MARVICH, MARIA	

ART UNIT	PAPER NUMBER
1636	16

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,809	POSSEE ET AL.	
	Examiner	Art Unit	
	Maria B Marvich, PhD	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *21 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 April 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This office action is in response to an amendment filed 4/21/03, Paper No. 14. Claim 27 has been amended and no new Matter has been added by this amendment. Claims 27-50 are pending in this application.

Response to Amendment

Receipt of Formal Drawings filed 4/21/03, Paper No. 14, is acknowledged. Objections to drawings have been withdrawn in light of approval of Formal Drawings by the Draftsman.

Receipt of a Supplemental IDS filed 4/21/03, Paper No. 12, is acknowledged. The documents have been considered as is noted on the signed PTO form 1449 that accompanies this office action.

Receipt of a substitute Paper Copy of the Sequence listing, a substitute Computer Readable Form of the Sequence Listing and a letter stating that no new matter has been added filed 4/23/03, Paper No. 15, is acknowledged. Objections to the Specification due to sequence disclosures that were not identified by SEQ ID Nos. are withdrawn in light of submission of corresponding SEQ ID NOs..

Rejection of claims 27-34 under 35 U.S.C. 102(b) as being anticipated by Blissard et al. US patent 5,750,383 (May 12, 1998) are withdrawn in light of amendment to claims.

Specifically, the limitation that the baculovirus vector is capable of being maintained in an intermediate host has been added. Blissard et al do not anticipate this limitation.

Rejection of claims 27-32 under 35 U.S.C. 102(e) as being anticipated by Clark et al. US patent 6,225,060 B1 (May 1, 2001) is withdrawn in light of amendment to claims. Specifically, the limitation that the baculovirus vector is capable of being maintained in an intermediate host has been added. Clark et al do not anticipate this limitation.

Rejections

This office action is not final, as new grounds of rejection have been made herein that were not necessitated by applicant's amendment.

Claim Objections

Claims 35-42 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form. Claims 27-34 already recite that the baculovirus vector is capable of being maintained in an intermediate host. Appropriate correction is required.

Applicant is advised that should claims 27-34 be found allowable, claims 35-42 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing,

despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 27-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. in view of Patel et al. (formally referred to as Nasmyth et al.) (NAR, Vol 20 pp97-104). **This rejection is maintained for reasons of record in the office action filed 12/18/02, Paper No. 11 and restated below.**

Applicants claim a method of cloning a gene comprising the steps of providing a replication-deficient baculovirus vector and a "rescue" vector encoding a nucleic acid that restores replication and a transgene. Functional genes are lacking the baculovirus vector such as lef genes and *ie*. The vector is furthermore capable of being maintained in an intermediate host such as yeast or bacteria.

Clark et al. teach use of a baculovirus vector for expression of genetic material. As shown in figure two, the method involves cloning of a cDNA of interest by providing an insect cell with baculovirus DNA deleted of p35 and orf-1629 and a linear DNA comprised of baculovirus DNA and a p35 gene and a orf-1629 gene. Co-transfection yields recombinant

baculovirus without utilizing cloning steps (column 5, line 1-7). Clark et al do not teach the use of a baculovirus vector that can replicate in yeast cells as well as insect cells.

Nasmyth et al. teaches use of a baculovirus vector that can replicate in Saccharomyces cerevisiae as well as insect cells. A shuttle vector YCbv was generated that could be used to grow in bacteria and yeast and could be used as a recipient of transgene insertion through homologous recombination (page 100, column 1, line 1-8). Nasmyth does not teach a replication defective baculovirus whose replication function is provided in trans by the transgene-carrying vector. Nasmyth and Clark are analogous art as both are improved methods for gene cloning utilizing baculovirus as a vector.

One of ordinary skill would have been motivated to use the method of Nasmyth et al. to clone the baculovirus of Clark et al. for the expected benefit of reducing time consumption (Nasmyth, page 97, column 2, third paragraph) and reducing cost due to the lack of need for rounds of plaque purification and the ability to isolate multiple recombinants simultaneously (Nasmyth et al, page 103, column 2, first paragraph). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Clark et al. with the methods of Nasmyth et al. by the addition of yeast selectable markers to the baculovirus of Clark et al. such that a baculovirus vector that can replicate in yeast is produced. Given the teachings of the cited art and the level of skill of the ordinary skilled artisan at the time of the applicant's invention, it must be considered that said ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claims 27-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitts et al. (Biotechniques, Vol 14 pp 810-817), cited by applicant, in view of Patel et al. (NAR, Vol 20 pp 97-104). **This is a new rejection.**

Applicants claim a method of cloning a gene comprising the steps of providing a replication-deficient baculovirus vector and a "rescue" vector encoding a nucleic acid that restores replication and a transgene. Functional genes such as *lef, ie* and *ORF1629* are removed from the baculovirus vector. The vector is furthermore capable of being maintained in an intermediate host such as yeast or bacteria.

Kitts et al. teach use of a method for producing recombinant Baculovirus in which an essential gene for replication is removed from or inactivated from the viral genome (figure 1). Cells are transfected with a transfer vector (i.e.BacPAK5 and BacPAK6) that contain the essential gene *ORF1629* linked to a target gene. The baculovirus is rescued following recombination between the genome and BacPAK5 or 6 and able to propagate normally (page 811, column 3, last paragraph). The target gene is then contained in the Baculovirus genome. Kitts et al do not teach that the baculovirus vector can be maintained in an intermediate host such as yeast or bacteria.

Patel et al. teaches use of a baculovirus vector that can replicate in Saccharomyces cerevisiae as well as in insect cells. A shuttle vector YCbv was generated that could be used to grow in bacteria and yeast and could be used as a recipient of transgene insertion through homologous recombination (page 100, column 1, line 1-8). Patel et al. do not teach a replication defective baculovirus whose replication function is provided in trans by the transgene-carrying

vector. Patel et al. and Kitts et al. are analogous art as both are methods for gene cloning utilizing baculovirus as a cloning vector.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Kitts et al. that teaches cloning of a foreign gene by restoring replication function to a replication defective baculoviral genome with the teachings of Patel et al. concerning replication and maintenance of the baculoviral genome in yeast because Kitts teaches that it is within the skill of the art to use replication defective baculovirus for cloning foreign genes and Patel et al teach that it is within the skill of the art to grow baculovirus in yeast. One of ordinary skill would have been motivated to combine the method of Patel et al. with the method of cloning a gene into baculovirus of Kitts et al. so that the baculovirus cloning vector can be propagated in a yeast cell for the expected benefit of reducing time consumption (Patel, page 97, column 2, third paragraph) and reducing cost due to the lack of need for rounds of plaque purification and the ability to isolate multiple recombinants simultaneously (Patel et al, page 103, column 2, first paragraph). Given the teachings of the cited art and the level of skill of the ordinary skilled artisan at the time of the applicant's invention, it must be considered that said ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claims 27-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blissard et al. US patent 5,750,383 (May 12, 1998) in view of Patel (Nasmyth) et al. (NAR, Vol 20 pp97-104). **This is a new rejection**.

Applicants claim a method of cloning a gene comprising the steps of providing a replication-deficient baculovirus vector and a "rescue" vector encoding a nucleic acid that restores replication and a transgene. Functional genes are lacking the baculovirus vector such as lef genes and *ie*. The vector is furthermore capable of being maintained in an intermediate host such as yeast or bacteria.

Blissard et al. teach use of a novel baculovirus cloning system in which an essential gene for replication is removed from or inactivated form the viral genome. Cells are transfected with a plasmid that contains the essential gene linked to a foreign gene. Thus the baculovirus is rescued and able to propagate normally (abstract). The essential genes include the immediate early genes (*ie*), *ie-1* and the *lef* genes (column 13, line 15-18). Blissard et al. does not teach that the baculovirus vector can be maintained in an intermediate host such as yeast or bacteria.

Patel et al. teaches use of a baculovirus vector that can replicate in Saccharomyces cerevisiae as well as insect cells. A shuttle vector YCbv was generated that could be used to grow in bacteria and yeast and could be used as a recipient of transgene insertion through homologous recombination (page 100, column 1, line 1-8). Patel et al. do not teach a replication defective baculovirus whose replication function is provided in trans by the transgene-carrying vector. Patel et al. and Blissard et al. are analogous art as both are improved methods for gene cloning utilizing baculovirus as a vector.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Blissard et al. that teaches rescue of a replication defective baculoviral genome through transfer of a foreign gene with the replication defective gene with the teachings of Patel et al. concerning replication and maintenance of the baculoviral genome in

yeast because Blissard et al. teach that it is within the skill of the art to use replication defective baculovirus for cloning foreign genes and Patel et al teach that it is within the skill of the art to grow baculovirus in yeast. One of ordinary skill would have been motivated to combine the method of Patel et al. with the method of cloning a gene into baculovirus of Blissard et al. so that the baculovirus cloning vector can be propagated in a yeast cell for the expected benefit of reducing time consumption (Patel, page 97, column 2, third paragraph) and reducing cost due to the lack of need for rounds of plaque purification and the ability to isolate multiple recombinants simultaneously (Patel et al, page 103, column 2, first paragraph). Given the teachings of the cited art and the level of skill of the ordinary skilled artisan at the time of the applicant's invention, it must be considered that said ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31-34 and 39-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the claimed invention. **This rejection is maintained for reasons of record in the office action filed 12/18/02, Paper No. 11 and is restated below.**

Applicants claim a genus of *lef1-12, dnapol, pl43, p35, ie-1, p47, ORF1629 and pp31* genes and functional fragments or mutations thereof.

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus. In the instant case, applicants only disclose *lef-2* but do not disclose functional fragments or mutations thereof. The prior art only teaches functional fragments through mutational analysis of the *ie-2* gene. Given the large size and diversity of the Baculovirus family (hundreds of different viruses), the diversity of the recited genes, the absence of disclosed or art recognized correlations between structure and function and the large number of potential fragments and mutations, it must be considered that any functional fragment or mutation must be empirically determined. By disclosing *lef-2*, the applicants have not reduced to practice the claimed invention and the relationship between structure and function is unclear. In an unpredictable art, the disclosure of one example in one genus would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 recites the step "causing" the recombination of the replication defective baculovirus vector and rescue vector. It is unclear what steps are required to be causative of the recombination.

Claim 29 is unclear for reciting "a gene necessary for restoring the functional gene". It is unclear if this gene is the functional gene required for viral replication or a gene that enzymatically restores the functional gene to its replication competent status.

Response to Arguments

Applicants traverse the claim rejections under 35 U.S.C 102(b) on page 10-11 of the amendment filed 4/21/03, Paper No. 14. Applicants argue that the baculovirus of Blissard et al. consists of whole virus particles whereas the present invention uses naked DNA from baculovirus. Further applicant argues that the system of Blissard et al. uses "an intermediate insect cell" containing a transfected gp64 to rescue the defective virus. While the virus contains gp64 in its coat, it lacks the gene for gp64.. Finally, applicant argues that the method of Blissard et al. generates low yield of virus. Therefore, the applicants argue that Blissard et al. do not teach, disclose or suggest the claimed invention.

Applicant's arguments filed 4/21/03 have been fully considered but they are not persuasive. That the vector of Blissard et al. are whole viral particles that contain gp64 in their

coat but do not contain the gene for gp64 is not a germane argument as the instantly recited composition is not limited to naked DNA and furthermore does not contain the limitation that it encode gp64. Blissard et al. teach a cloning system that utilizes a baculovirus vector in which a gene essential for replication, growth or propagation is removed. This vector is provided and a rescue gene linked to a foreign gene are "provided". As a non-limiting example of an essential gene, gp64 is removed from the baculovirus and is provided in trans by a cell line for the propagation of the virus but for cloning purposes it is provided by the rescue gene (column 2, line 36-59). A recombinant rescued baculovirus is then used to express the foreign gene (column 2, line 44-45). While the baculovirus is infected and the rescue gene is transfected, both "are provided" such that recombination can occur and the foreign gene is contained in a recombinant "nuclear polyhedrosis virus particle". That the method of Blissard et al generates virus of low yield is also not a germane argument as the instantly claimed invention recites a method for the cloning of a gene using a baculovirus vector as a cloning vehicle. No requirement for viral production of high yield is recited.

Applicants traverse the claim rejections under 35 U.S.C 103(a) on page 13-15 of the amendment filed 4/21/03, Paper No. 14. Applicants argue that the baculovirus vector of Clark et al. can only replicate in a cell line in which p-35 is not needed to prevent apoptosis from occurring. Referring to Fraser et al. and Clem et al., applicants state that *Trichoplusia ni* must be used therefore creating a heterogeneous population and a stock that is unusable for repeat experimentation or as a control. Further, applicant argues that the system of Clark et al can replicate at low levels in normal insect cells and therefore a stock of virus will be generated that is contaminated with non-insert containing vectors. While steps that require extra work and time

can reduce the relative levels of this parental virus, the instant invention does not require these additional steps. It is argued that Patel et al. is designed towards producing a recombinant baculovirus using intermediate yeast cells to modify and produce recombinant viruses. The instant invention efficiently produce vectors with foreign DNA and the intermediate host of the instant invention is not used to modify the baculovirus but simply for its replication. Finally, applicant argues that there is no teaching, motivation or suggestion to combine Clark with Patel. And that once combined, the resultant invention does not represent the present invention as the yeast cells are used as an intermediate host to produce recombinant viruses whereas the present invention uses an intermediate host simply to prepare the baculovirus vector.

Applicant's arguments filed 4/21/03 have been fully considered but they are not persuasive. There is no evidence that the vector of Clark et al may result in viral particles that are part of a heterogeneous population or that the vector replicates at low levels in normal insects generating a stock that is contaminated with non-insert containing vectors. The applicant relies upon Fraser et al. as evidence. However, Fraser et al. teach that nuclear polyhedron viruses mutants were the result of insertion of cellular DNA from *T. ni.* into the viral genomes contained within a 1280 bp AluI fragment. Clem et al. teach that in the absence of p-35, premature death resulted in SF-21 and BmN-4 cells but not *Tr. ni.* cells. Therefore, the applicant concludes that the p-35 mutant baculovirus genome must be grown in *Tr. ni.* and doing so will result in heterogeneous stocks that contain contaminated vectors. However, the method taught by Clark et al. does not require use of *Tr. ni* cells but instead utilizes SF-9 cells infected with the baculovirus genome deleted of p-35 with a rescue plasmid expressing p-35 to suppress apoptosis (figure 2). In example 4-example 8, Clark et al. utilize Sf9 cells, which are also used in the

instant invention and are designed for use in a high throughput assay for the generation of recombinant Baculovirus containing cloned DNA. There is neither a resultant heterogeneous population nor a stock of virus contaminated with non-insert containing vector. Therefore, it would not be expected absent evidence to the contrary that baculoviral clones generated according to the method of Clark et al. would be any different than the baculoviral clones generated by the instant invention. Motivation to combine Patel et al. and Clark et al., which both teach methods for the generation of recombinant baculovirus, is found in Patel et al. Patel et al. specifically addresses the need in recombinant technology utilizing baculovirus for a method that is rapid and efficient and ensure that there is not background of parental virus and that eliminates the need for time-consuming plaque assays. The solution according to Patel et al. is the propagation of the **viral genome** in yeast (page 103, column 1) and this method overcomes many difficulties and time-consuming aspects of existing methods. And on column 2, it is considerably more rapid and efficient than currently used methods and in addition is devoid of any background of parental, non-recombinant virus. A person of skill in the art would have been motivated to utilize a baculovirus vector that can be maintained in an intermediate host for rapid and efficient production to ensure that there is not background of parental virus and to eliminate the need for time-consuming plaque assays.

Applicants traverse the claim rejections under 35 U.S.C 112, first paragraph, on page 15-16 of the amendment filed 4/21/03, Paper No. 14. Applicants argue that the one of skill in the art would be able to identify functional fragments or mutations in a matter of routine and not undue experimentation. Applicant further argues that the genes *lef1-12, dnapol, pl43, p35, ie-1, p47,*

ORF1629 and pp31 are found universally in baculovirus and the assay for functionality is a simple one involving determination that replication is or is not enabled.

Applicant's arguments filed 4/21/03 have been fully considered but they are not persuasive. The skilled artisan cannot envision the detailed structure of the encompassed genes, functional fragments and/or mutations, regardless of the complexity or simplicity of the method of isolation. Applicants recite a large, divers and highly variant genus of essential Baculovirus genes *lef1-12, dnapol, pl43, p35, ie-1, p47, ORF1629 and pp31* functional fragments or mutations thereof. The single species, *lef-2*, specifically disclosed is not representative of the genus because the genus is highly variant. Neither the prior art nor the specification teaches a correlation between structure and function. The disclosure of a single species does not convey to the skilled artisan that the applicants were in possession of the claimed genus.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to patent analyst, Zeta Adams, whose telephone number is (703) 305-3291.

Maria B Marvich, PhD
Examiner
Art Unit 1636

June 30, 2003

PATENT EXAMINER
Gerald G. Letters Jr
A.U. 1636